REMARKS

An Office Action was mailed in the above-captioned application on September 13, 2007. Claims 1, 3-11, 13, and 15-21 were pending in the application. Claims 1, 3-11, 13, and 15-21 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

The Rejection of Claims 1-19 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1-19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area that applicants regard as their invention with a reasonable degree of precision and particularity.

Specifically, the rejection alleges that the claims are drawn to treating prostate cancer due to the recitation of "a patient with prostate cancer" in Claims 1 and 10 but that "alleviating a symptom" is irrelevant to the treatment of prostate cancer because symptom are not causes of diseases.

Applicant believes that Claims 1 and 10 are clear as written, since symptoms result from or are manifestations of diseases or conditions and do not cause them, as explained in detail in the previous response. Solely in the interest of expediting prosecution, however claims 1 and 10 have been amended to recite that the symptom of prostate cancer is selected from the group consisting of prostatic enlargement, pelvic pain (claim 10 only) urinary incontinence, urinary retention, urge-type dysfunction, unstable bladder, unstable sphincter, and recurrent urinary infection. It is believed that the amendment clarifies that the symptoms are symptoms of prostate cancer in a patient with prostate cancer. In view of these amendments, Claims 2 and 13 have been cancelled.

The rejection also states that the claimed invention is indefinite for failing to particularly point out and distinctly claim what is intended by "a therapeutic amount of a botulinum toxin." Example 2 describes shrinkage of prostate volume in rats injected with varying amounts of botulinum toxin, thereby demonstrating botulinum toxin's effects on the prostate. Furthermore,

Example 3 describes the treatment of a patient with prostate cancer with one 200 IU injection of botulinum toxin into the external urethral sphincter and the resulting relief from the prostate cancer symptom of pain. Based on this disclosure, Applicant submits that the recitation "a therapeutic amount of a botulinum toxin" is clear.

In view of the foregoing amendments, the Examiner is respectfully requested to reconsider the rejection under 35 U.S.C. § 112, second paragraph.

The Rejection of Claims 1-19 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-19 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). With this standard in mind, the rejections raised by the Examiner are discussed below.

The claims as amended are directed to a method of alleviating a symptom of prostate cancer, the method comprising the step of administering a therapeutic amount of botulinum toxin type A into the prostate gland or a portion of the lower urinary tract of a patient with prostate cancer, thereby alleviating a symptom of prostate cancer, wherein the symptom of prostate cancer is prostatic enlargement, pelvic pain (claim 10 only) urinary incontinence, urinary retention, urge-type dysfunction, unstable bladder, unstable sphincter, and recurrent urinary infection.

Specifically, the rejection states that "the breadth of the claims is directed to prostate cancer treatment . . . ." The rejection also states that "treatment or cure of prostate cancer" with botulinum toxin is unpredictable. The rejection also states that "the specification does not provide examples of treating prostate cancer or curing prostate cancer." As the claims have been amended to recite alleviation of specific symptoms of prostate cancer and botulinum toxin type A, Applicant submits that they are fully enabled over the entire scope of alleviating symptoms of prostate cancer in patients with prostate cancer for the reasons of record which were detailed in the previous Office action response.

Applicant further notes that Example 2 describes shrinkage of prostate volume in rats injected with varying amounts of botulinum toxin, thereby demonstrating botulinum toxin's effects on the prostate. Furthermore, Example 3 describes the treatment of a patient with prostate cancer with one 200 IU injection of botulinum toxin into the external urethral sphincter and the resulting relief from the prostate cancer symptom of pain. As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). Applicant submits that Examples 2 and 3 provides a reasonable correlation with the treatment of symptoms of prostate cancer.

The rejection states that the effects and doses of various types of botulinum toxin in the method are not disclosed in the specification, and that one cannot correlate generic therapeutic amount of botulinum toxin B, C, D, E, F and G as claimed. Applicant disagrees with this assertion; however, solely in the interest of expediting prosecution, Claims 1 and 10 have been amended to recite that the botulinum toxin is a botulinum toxin type A. In view of this amendment, claims 6-8 and 16-17 have been cancelled.

In summary, Applicant has provided a specification which describes the alleviation of symptoms of prostate cancer with botulinum toxin type A through a detailed description of the invention and working examples as detailed here and in the previous response. The description provides a reasonable correlation between the disclosed methods and the claimed subject matter. Applicant therefore submits that the pending claims are fully enabled and respectfully requests reconsideration.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. Applicant attempted on several occasions to schedule a telephonic interview with the Examiner to discuss the final rejection; however, no interview was scheduled. Should there be any outstanding issues in this application, the Examiner is invited to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: /Darla G. Yoerg/
Darla G. Yoerg
Registration No. 48,053
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

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